EXHIBIT 1



Transcript of the Testimony of:

Susan Mitmesser, Ph.D.

Korolshteyn

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Costco Wholesale Corporation and NBTY, Inc.

March 28, 2017

Volume I

CONTAINS TESTIMONY DESIGNATED AS ATTORNEYS' EYES ONLY
PAGES 19 AND 22

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1		UNITED STATES DISTRICT COURT
2		SOUTHERN DISTRICT OF CALIFORNIA
3		
4	TATIANA KO	ROLSHTEYN, on behalf of
5	herself an	d all others similarly
6	situated,	
7	Plai	ntiff,
8		Case No. 3:15-cv-00709-CAB-RBB
9	-vs-	
10	COSTCO WHO	LESALE CORPORATION
11	and NBTY,	INC.,
12	Defe	ndants.
13		/
14	VI	DEOTAPED DEPOSITION
15	CONTAINS T	ESTIMONY DESIGNATED AS ATTORNEYS' EYES ONLY (PAGE 19 AND 22)
16	DEPONENT:	SUSAN MITMESSER, PH.D.
17	DATE:	Tuesday, March 28, 2017
18	TIME:	10:02 a.m.
19	LOCATION:	Liberty Center
20		100 West Big Beaver Road, Suite 200
21		Troy, Michigan
22	REPORTER:	Maureen M. McLaughlin, CSR-4400
23		Litivate Reporting & Trial Services
24	VIDEO:	Jeremy Ramsden
25		Litivate Reporting & Trial Services

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25	

1 Okay. And your report is intended to purportedly Ο. 2 support the claims made by defendants about their --3 their Gingko biloba products? 4 Yes. Α. 5 Doctor Mitmesser, would it be safe to say that the Ο. question that is to be answered is whether or not 6 7 long-term administration of Gingko biloba supports 8 brain health, memory or cognitive function in healthy 9 persons? 10 MR. DELGADO: Objection, calls for a legal conclusion. You can answer. 11 12 THE WITNESS: No. 13 BY MR. WELTMAN: 14 Q. No? 15 The question I was -- my expert report is to provide Α. 16 substantiation for the claims on the label. 17 Okay. And, again, what do you understand the claims 0. 18 on the label to mean? 19 Supporting -- supporting memory. 20 Anything else? Q. Memory and -- I don't have the exact wording in my --2.1 Α. 22 in my head, but supporting memory and cognitive 23 function. 24 And in what population of persons? Healthy persons? Q. 25 Sick persons? Persons with Alzheimer's? What -- what

1		population persons are you talking about?
2	Α.	That's not indicated.
3	Q.	That's not indicated on the labeling?
4	Α.	Correct.
5	Q.	Isn't it true that defendants' Ginkgo biloba products
6		are not intended to treat or cure diseases such as
7		Alzheimer's disease or dementia?
8	Α.	Correct.
9	Q.	Okay. Doctor Mitmesser, in your own words, why do you
10		think you are qualified to render the opinions you
11		have rendered in this report?
12	A.	Because of my educational background and my industry
13		knowledge.
14	Q.	Okay. Because of your educational what?
15	A.	Background. Can you not hear me properly?
16		THE VIDEO OPERATOR: He's not going to hear
17		on that. If you want to slide that microphone
18		THE WITNESS: Oh.
19		THE VIDEO OPERATOR: up a little bit
20		further towards you. There you go. That may help.
21		THE WITNESS: Thank you.
22	BY N	MR. WELTMAN:
23	Q.	Because of your educational background and your
24		industry experience?
25	Α.	That's what I said, yes.

1		execution of clinical trials related to Alzheimer's or
2		dementia.
3	Q.	Okay. That's your professional career, correct?
4	Α.	Correct.
5	Q.	Okay. And in your undergraduate or postgraduate
6		training, did you ever learn the the treatment of
7		Alzheimer's disease or dementia?
8	Α.	I'm sorry. You were breaking up. Can you repeat the
9		question, please.
10	Q.	No problem. And there's somebody who's got papers
11		that are right next to the microphone, so that's why I
12		broke up. If they could stop moving those, I would
13		appreciate it, but, anyways, in your undergraduate or
14		postgraduate training, did you study the treatment of
15		Alzheimer's disease and/or dementia?
16	Α.	Yes.
17	Q.	When?
18	A.	I don't recall the date.
19	Q.	Okay. Could you describe the course or courses that
20		you took?
21	Α.	I took a course on I don't recall the title, but it
22		was around acute conditions and long-term conditions.
23		And the long-term Alzheimer's and dementia was a
24		condition that was highlighted as an example of a
25		long-term condition.

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1	Q.	I'm sorry. Dementia was one of the things you
2		studied?
3	A.	Yes.
4	Q.	Okay. And did you study Alzheimer's disease too?
5	A.	I I I apologize. I don't have a I don't
б		remember the course outline, but dementia being the
7		overarching category and Alzheimer's being a
8		subcategory of dementia, there were if I recall
9		correctly, there were quite a few there were quite
10		a few subcategories of dementia that were highlighted
11		in the course.
12	Q.	And do you recall when you took this course?
13	A.	No.
14	Q.	Was it in postgraduate?
15	A.	Yes.
16	Q.	Okay. And what do you recall you learned about
17		dementia in that course?
18	A.	Some of the test measures, so some of the clinical
19		endpoints. I I I can't recall specifics. It
20		was quite some time ago.
21	Q.	How long ago was it?
22	Α.	I would guess anywhere from fifteen to twenty years
23		ago.
24	Q.	Okay. So do you recall what clinical endpoints you
25		studied?

1	A.	Not specific to that course.
2	Q.	Okay. Do you recall the the test measures that you
3		studied?
4	Α.	Not specific to the course.
5	Q.	When you say not specific to the course, you learned
6		something about this later in your career?
7	A.	Correct.
8	Q.	Was that after you got involved in this litigation?
9	A.	After I got no.
10	Q.	You learned it before you got involved in this
11		litigation?
12	A.	Correct.
13	Q.	When?
14	A.	Throughout my professional career we I've been
15		involved in I've been involved in looking at how
16		the brain how we look at memory and how we
17		clinically can measure, things of that nature.
18	Q.	Okay. During your career you say you looked at how we
19		look at memory and how we can measure that. When was
20		that?
21	Α.	I don't recall a specific date.
22	Q.	What jobs did you do that in?
23	A.	I did it when I was at MDS Pharma Services, when I was
24		at Mead Johnson Nutrition, and since I've been at the
25		Nature's Bounty company.

1		the record. The time is 10:26 a.m.
2		(Whereupon an off-the-record discussion was
3		held.)
4		THE VIDEO OPERATOR: We are now back on the
5		record. The time is 10:29 a.m.
6		MR. WELTMAN: Okay. Counsel, you had a
7		chance to confer with Doctor Mitmesser. Are you still
8		instructing her not to answer?
9		MR. DELGADO: I did confer with her and I
10		will allow her to answer, and I will designate this
11		answer as attorneys' eyes only under the protective
12		order in this case.
13		MR. WELTMAN: All right. Thank you.
14	BY MI	R. WELTMAN:
15	Q.	So what was it that you worked on at MDS Pharma
16		Services?
17	A.	Philip Morris was doing some clinical trials looking
18		at the effects of cigarettes on certain memory,
19		cognitive function, et cetera.
20	Q.	And what was your involvement in that project?
21	A.	I was a medical writer, so I
22	Q.	So
23	A.	Do you want me to go?
24	Q.	Go ahead.
25	7\	So I looked at the data, the results, helped interpret
	A.	50 1 100ked at the data, the results, helped interpret

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1		it and wrote up the findings in a variety of forms, so
2		whether that was a ICH document form or variety of
3		documents.
4	Q.	Okay. Anything else at MDS Pharma Services?
5	Α.	Related to cognition?
6	Q.	Brain.
7	A.	Brain.
8	Q.	Cognition, brain.
9	Α.	Not that I recall.
10	Q.	And you were not the researcher on that Philip Morris
11		project, correct?
12	Α.	You are correct.
13	Q.	You didn't design the study?
14	Α.	Correct.
15	Q.	You just wrote up something for the researchers to
16		read?
17	Α.	No. I helped with the interpretation of the data,
18		looked at the data, worked very closely with the
19		statisticians and then wrote up documents.
20	Q.	Okay. And at Mead Johnson you were working with
21		nutrition for infants; is that correct?
22	Α.	Infants, young children and pregnant women.
23	Q.	Okay. And this had to do with either nutrition for
24		infants or prenatal nutrition?
25	Α.	And nutrition for young children.

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1	Q.	How old?
2	A.	I think at the time we were looking at children I want
3		to say around age eight.
4	Q.	And this had to do with formulas, nutrition formulas?
5	A.	Not solely.
6	Q.	What else?
7	A.	For children, children older than an infant, they were
8		ready-to-drink beverages. For pregnant women,
9		prenatal, it we did things related to they
10		were things were delivered via solid dose, so a
11		capsule, a gel cap.
12	Q.	And
13	A.	And infant formula.
14	Q.	I'm sorry?
15	A.	And infant formula.
16	Q.	Okay. And these were related to the brain development
17		of either fetuses, infants or young children?
18	A.	Some of the research was.
19	Q.	What what part of the research was?
20	A.	I'm not sure I understand your question as to what
21		part of the research. Do you want a percentage or
22		I'm not sure I understand the question.
23	Q.	You said some of the research related to brain
24		development.
25	A.	Uh-huh.

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1	Q. My question is is what was that research?
2	A. Oh, what was the research. We in infants, as an
3	example, we looked at brain development, brain
4	maturation. Also related to that was visual acuity.
5	Q. And what substances, if any, were you looking at with
6	regard to these brain issues?
7	A. Again, I would say that this is the same
8	confidentiality
9	MR. DELGADO: Okay. I'll mark this as
10	attorneys' eyes only as well.
11	THE WITNESS: Okay. We we looked at
12	different ratios of fatty acids, probiotics,
13	prebiotics, some different types of proteins, so
14	things such as Lactoferrin.
15	BY MR. WELTMAN:
16	Q. And this was with respect to brain development,
17	correct?
18	A. In most of I shouldn't say that. In a lot of the
19	research that Mead Johnson performs, one component
20	that they look into is around cognitive brain
21	development, so that's I want to be fair that
22	that's not the only reason that they do these trials,
23	so they're looking at a lot of different endpoints,
24	brain development, cognition being one of those.
25	Q. Was Ginkgo biloba one of the products in any one of

1		the ingredients in any of these Mead Johnson products?
2	Α.	I don't recall that it was.
3	Q.	Okay. And again, and I may have asked you this,
4		but I'll ask it again. During your educational career
5		or your professional career, have you ever studied or
6		been involved with the treatment of Alzheimer's
7		disease or dementia prior to your employment at NBTY?
8	Α.	No.
9	Q.	And prior to this litigation you had done no study or
10		training about blood flow to the brain, correct?
11	Α.	No, that's not correct.
12	Q.	Okay. And why is that not correct?
13	A.	Degayge I look at a let of different ingredients and
13	Α.	Because I look at a lot of different ingredients and
14	Α.	the effect of those ingredients and nutrients on brain
	Α.	
14	Q.	the effect of those ingredients and nutrients on brain
14 15		the effect of those ingredients and nutrients on brain function.
14 15 16		the effect of those ingredients and nutrients on brain function. Okay. Do you recall giving your deposition previously
14 15 16 17	Q.	the effect of those ingredients and nutrients on brain function. Okay. Do you recall giving your deposition previously in this case?
14 15 16 17 18	Q.	the effect of those ingredients and nutrients on brain function. Okay. Do you recall giving your deposition previously in this case? Yes.
14 15 16 17 18 19	Q. A. Q.	the effect of those ingredients and nutrients on brain function. Okay. Do you recall giving your deposition previously in this case? Yes. Do you recall you were sworn under oath at that time?
14 15 16 17 18 19 20	Q. A. Q. A.	the effect of those ingredients and nutrients on brain function. Okay. Do you recall giving your deposition previously in this case? Yes. Do you recall you were sworn under oath at that time? Yes.
14 15 16 17 18 19 20 21	Q. A. Q. A.	the effect of those ingredients and nutrients on brain function. Okay. Do you recall giving your deposition previously in this case? Yes. Do you recall you were sworn under oath at that time? Yes. And at the time did you tell the truth?
14 15 16 17 18 19 20 21 22	Q. A. Q. A. Q.	the effect of those ingredients and nutrients on brain function. Okay. Do you recall giving your deposition previously in this case? Yes. Do you recall you were sworn under oath at that time? Yes. And at the time did you tell the truth? Yes.
14 15 16 17 18 19 20 21 22 23	Q. A. Q. A. Q.	the effect of those ingredients and nutrients on brain function. Okay. Do you recall giving your deposition previously in this case? Yes. Do you recall you were sworn under oath at that time? Yes. And at the time did you tell the truth? Yes. And do you recall receiving being asked the

1		been proven to treat any of the symptoms of dementia?
2		Strike that. Do you believe that I'm sorry. Let
3		me rephrase it. Do you believe that Ginkgo biloba has
4		been proven effective in the treatment of any of the
5		symptoms of dementia?
6	Α.	There is evidence that Ginkgo so the symptoms of
7		dementia. Can you define that, please.
8	Q.	Well, okay. I'll ask you. What do you understand the
9		symptoms of dementia to mean?
10	Α.	I would say affecting memory, recognition, recall.
11		Those are some symptoms. You could also look at
12		things like tinnitus, vertigo.
13	Q.	Okay. Do you believe with that definition, do you
14		believe that Ginkgo biloba has been proven effective
15		in the treatment of any of the symptoms of dementia?
16	A.	I would not use the words "proven" "proven
17		effective".
18	Q.	So you do not believe that Ginkgo biloba has been
19		proven effective to treat any of the symptoms of
20		dementia, correct?
21	Α.	There is evidence that Ginkgo supports those
22		supports the improvement of some of those symptoms.
23	Q.	Okay. You say supports, but my my question still
24		is has Ginkgo biloba been proven effective to treat
25		any of the symptoms of it?

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1	disease strike that. Is it is it your opinion
2	that Ginkgo biloba strike that. Is it your opinion
3	that the evidence you've seen about Ginkgo biloba and
4	its purported improvement of the symptoms of dementia
5	is sufficient that persons with these conditions
6	should take Ginkgo biloba?
7	MR. DELGADO: Objection, calls for
8	speculation. Go ahead.
9	THE WITNESS: May I ask the court reporter
10	to re-read that. That was I want to make sure I
11	caught it all.
12	MR. WELTMAN: Please.
13	(Whereupon the record, as requested, was
14	read back by the court reporter.)
15	THE WITNESS: No.
16	BY MR. WELTMAN:
17	Q. And I probably asked this before, but defendants'
18	Ginkgo biloba products are not marketed to treat
19	either Alzheimer's disease or dementia, are they?
20	A. Correct.
21	Q. And they're not marketed to treat any disease,
22	correct?
23	A. Correct.
24	Q. Isn't it true that studies involving Ginkgo biloba in
25	either the treatment of Alzheimer's disease or

1		dementia have no bearing on whether Ginkgo biloba
2		provides healthy persons with support of brain health,
3		memory or cognitive function?
4	A.	I don't agree with that statement.
5	Q.	So you believe that studies involving Ginkgo biloba on
6		persons with either Alzheimer's disease or dementia
7		can have a bearing on whether Ginkgo biloba provides
8		healthy persons with support of brain health, memory
9		or cognitive function?
10	A.	I think studying again, these are not novel
11		molecules, okay, so these are not pharmaceutical
12		drugs. I think studying a nutrition ingredient
13		nutrient in a stressed system, biological system gives
14		us evidence to understand the extent in which
<mark>15</mark>		something may benefit.
16	Q.	Benefit whom?
17	A.	Benefit the population being studied.
18	Q.	Okay. But if the population being studied is either
19		persons with Alzheimer's disease or dementia, how do
20		the results of that study in any way become
21		extrapolatable to people who are healthy?
22	Α.	I didn't say we I would extrapolate a study
23		specifically on dementia or Alzheimer's to healthy
24		people. What I said was it is beneficial to
25		understand how a ingredient reacts in a stressed

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1	system, and stress can be in a disease state or in a		
2		temporary stress state such as exercise. It helps us	
3		understand what's going on in that biological system.	
4	Q.	And in the case of somebody with Alzheimer's or	
5		dementia, the biological system is a person with	
6		Alzheimer's or dementia, correct?	
7	A.	Yes.	
8	Q.	You have your report in front of you. Could you	
9		identify which studies you've cited in your report	
10		that involve Ginkgo biloba and whether or not it	
11		supports brain health, memory or cognitive function in	
12		persons without a disease.	
13	A.	Do you mind if I look?	
14	Q.	No. Of course.	
15	A.	Okay.	
16	Q.	Take a look.	
17	A.	Thank you.	
18		MR. WELTMAN: By the way, are you folks	
19		going to want to know want to take a little lunch	
20		break at some point in time, just so I know?	
21		MR. DELGADO: No. I think we'll just keep	
22		going through.	
23		MR. WELTMAN: Okay. Court reporter,	
24		videographer okay with that?	
25		MR. DELGADO: It's a three hour total dep.	

1		our labels.		
2	Q.	And in order to substantiate the claims on your		
3		labels, don't you have to look at the totality of the		
4		evidence?		
5	Α.	Yes.		
6	Q.	And you did cite Alzheimer's and dementia studies in		
7		purported support of defendants' claims, correct?		
8	Α.	Correct.		
9	Q.	So why did you ignore the DeKosky study which studied		
10		three thousand and sixty-nine subjects?		
11	Α.	Again, the report was written to support the claims on		
12		our labels.		
13	Q.	Doctor, I we've done some arithmetic here, and the		
14		total of all of your Alzheimer's disease and dementia		
15		studies that you cite in your report total a total of		
16		three hundred and eighty-nine patients. And my		
17		question to you well, if you do the math, the		
18		DeKosky study is almost seven times larger than the		
19		total of all the Alzheimer's disease and dementia		
20		studies you cite, and my question to you is how could		
21		you not at least discuss the DeKosky study in your		
22		report?		
23		MR. DELGADO: Objection, calls for a legal		
24		conclusion.		
25		THE WITNESS: Again, that was not the		

	Susan Milinesser, Fir.D. March 20, 2017		
1		have that information.	
2	Q.	Okay. Wouldn't you agree that the Snitz study is at	
3		least a very highly relevant study to the question of	
4		whether or not defendants' statements about their	
5		Ginkgo biloba products are truthful or not?	
6	A.	No.	
7	Q.	And why is that?	
8	A.	Well, there are a couple of flaws with the study.	
9	Q.	Yeah.	
10	A.	Yeah.	
11	Q.	What?	
12	A.	They had significant missing data points and so they	
13		inputted carried over data points. In addition, this	
14		was an intent-to-treat population, so it's taking	
15		in the statistical analysis is taking into all	
16		subjects that were randomized and regardless of those	
17		subjects adhered to treatment. And so a more	
18		appropriate a more appropriate statistical analysis	
19		would have been a per-protocol analysis.	
20	Q.	So you believe that intent-to-treat analyses are less	
21		appropriate than per-protocol analyses?	
22	Α.	That's not what I said.	
23	Q.	Well, you said that in this in this study	
24	А.	Uh-huh.	
25	Q.	a per-protocol analysis would be more appropriate	

1 no? 2 Α. Yes. 3 Ο. And are you aware of the Alzheimer's organization or association? 4 5 I know there's an organization. I'm not sure that's Α. 6 the name. 7 Well, are you familiar with the fact that the 0. Alzheimer's organization does not recommend Ginkgo 8 9 biloba for the treatment of anything related to 10 Alzheimer's? 11 A. I'm -- was not aware of that. 12 Well, if it was, in fact, the case, would you disagree 0. 13 with the Alzheimer's organization? 14 Α. Our product is not intended to treat Alzheimer's. Okay. But, again, I heard just a minute ago that you 15 Q. said it was effective in the treatment of some 16 17 symptoms of Alzheimer's, --18 A. And I --19 O. -- correct? You're absolutely right. It is effective. 20 O. And so if the Alzheimer's organization says that you 2.1 22 shouldn't take Ginkgo biloba for Alzheimer's, you 23 would disagree with the Alzheimer's organization, 24 wouldn't you? 25 A. Yes.

INSTRUCTIONS FOR READING/CORRECTING YOUR DEPOSITION

To assist you in making corrections to your deposition testimony, please follow the directions below. If additional pages are necessary, please furnish them and attach the pages to the back of the errata sheet.

This is the final version of your deposition transcript.

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After completing your review, please sign the last page of the errata sheet, above the designated "Signature" line.

ERRATA SHEET

Page	Line	
5	_9_	Change:Mitmesser
		Reason:incorrect spelling
25	14	Change: but there was more than 1 study; we
conduct	ed numerous	studies
		Reason: 1 study was not accurate
26	10	Change: an appropriate
		Reason: incorrect as written
26	11	Change: an appropriate
		Reason: incorrect as written

Page	Line	Change:strike 'so'
43	5	Reason:incorrect as written
		Change:add 'account' after into
66	15	Reason:not complete as written
		Change:change 'of' to 'if'
66	16	Reason:incorrect
		Change:
		Reason:
		Change:
		Reason:
		Change:
		Reason:
		Change:
		Reason:
		Change:
	Subject to	o the above changes, I certify that the transcript is true and correct.
	No chang	es have been made. I certify that the transcript is true and correct.
		1 1
,	2	11/10
<u> </u>		28 April 2017
Signature	;	Date